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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,695	01/16/2004	Gerianne Tringali DiPiano	FEM 105	8448
23579 7590 05/13/2008				
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EXAMINER				
VU, QUYNH-NHU HOANG				
ART UNIT		PAPER NUMBER		
3763				
MAIL DATE		DELIVERY MODE		
05/13/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/759,695

Applicant(s)

DIPIANO ET AL.

Examiner

QUYNH-NHU H. VU

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

Amendment and Request for Continued Examination (RCE) filed on 3/20/08 has been entered.

Claims 1-6, 8 are present for examination.

Claim 7 is cancelled.

Response to Arguments

Applicant's arguments with respect to claims 1-6, 8-10 have been considered but are moot in view of the new ground(s) of rejection. See below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6, and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones (US 2,847,011).

Jones discloses a vaginal or rectal applicator comprising: an applicator barrel 11 comprises a medication chamber 15 at the proximal end of the applicator; wherein the medication chamber has a smaller diameter than the diameter of the applicator barrel and wherein the medication chamber is designed to contain up to 1mL of a pharmaceutical (col. 2, lines 63-64; the pharmaceutical composition is in form selected from the group consisting of powder, gel, cream or lotion (col. 1, lines 15-20); and wherein the proximal end of the applicator contains an opening suitable for filling the medication chamber with the pharmaceutical composition and dispensing the pharmaceutical composition from the medication chamber; and wherein the applicator barrel comprises a barrier 21 or 14 proximal to the opening; a

Art Unit: 3763

plunger 10; a plunger tip 16; an applicator cap 18 is removable from the proximal end of the applicator barrel;

Regarding claims 6, 8-10, they encompass the same scope of the invention as to that of claims 1-5 except they are drafted in method format instead of apparatus format. These steps must be performed in order to obtain the device. Therefore, the method of performing or transvaginal or transrectal drug delivery would be inherent to the shown structure of the device.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2 are rejected under 35 U.S.C. 103(a) as obvious over Jones.

Jones discloses the invention substantially as claimed. Jones does not disclose the applicator further comprises a flange. However, it is well-known in the medical art or a container art to provide an applicator with the flange for the user manually handle easily.

Claims 4-5 are rejected under 35 U.S.C. 103(a) as obvious over Jones in view of Yeager et al. (US 6,224,573).

Jones discloses the invention substantially as claimed. Jones does not specifically disclose that applicator cap and plunger tip are formed an air tight seal with the applicator barrel.

Yeager disclose that an applicator cap 12 formed an air-tight seal with the applicator barrel 14 (col. 2, lines 7-15, col. 3, lines 5-29); the plunger tip 92 formed an air-tight seal with the applicator barrel (col. 6, lines 41-61).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Jones with the applicator cap and plunger tip formed air-tight seal, as

Art Unit: 3763

taught by Yeager, in order to provide a tight friction fit relationship between the cap; the plunger with the barrel.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763